

REMARKS/ARGUMENTS

Claims 1-6, 10, 12, 14-18, 65-68 are active. Claims 7-9, 11, 13, and 19-64 have been withdrawn from consideration. Claim 1 has been amended to remove non-elected subject matter (without prejudice to its appearance in a Divisional Application), to require a mutation at W550 and to include a functional limitation. Claims 67-68 find support in claim 1. No new matter is believed to have been added. Favorable consideration of these amendments and allowance of the case are respectfully requested.

Interview Summary Record

The Applicants appreciate the courteous and helpful interview with Examiner Hutson conducted on March 3, 2011. It is believed that agreement was reached with respect to enablement of the claims as directed to polypeptides comprising a mutation at W550 that have DNA polymerase activity. The Examiner requested additional information about the deposited biological materials named in claim 65. The double patenting rejection of claim 65 was reviewed and was indicated to be based on the appearance of two of the species named in claim 65 in a prior patent. Applicants were advised to look at claim 4 of U.S. Patent No. 7,417,133 to avoid potential double patenting rejections.

Restriction/Election

The Applicants previously elected with traverse **Group I**, claims 1-18, 65 and 66, directed to polynucleotides. A provisional election for examination purposes only was made of the following species: (1) polynucleotide sequences encoding for polypeptides having 80% identity to residues 13-555 of SEQ ID NO: 26, wherein said polypeptide has at least one mutation, at position **W550** (position 827 of the Taq polymerase wild-type) (at least claims 1-18, 65 and 66 readable thereon); and (1) polynucleotide SEQ ID NO:21 (at least claims 1-18,

65 and 66 readable thereon). The requirement has been made FINAL. The Applicants respectfully request that the claims of the nonelected group(s) or other withdrawn subject matter which depend from or otherwise include all the limitations of an allowed elected claim, be rejoined upon an indication of allowability for the elected claim, see MPEP 821.04.

#### Objection—Claims

Claims 1, 3-6, 10, 12, 14-18, 65 and 66 were objected to as containing non-elected subject matter. This objection is moot in view of the removal of the nonelected subject matter from the claims. Claim 1 has been revised to address the Examiner's objection set forth on page 3 of the Advisory Action. Claim 1 encompass polynucleotide sequences encoding a polypeptide which has a mutation at W550 and may contain other mutations within the 95% homology parameters. This claim language is consistent with the election made on January 4, 2010.

#### Objection—Specification

Page 34 of the specification was objected to as being unclear as to what the monoclonal phages containing or how they were generated. Page 34 as well as claim 65 describes deposited monoclonal phages and thus meets the requirements of 35 U.S.C. 112, first paragraph. See MPEP 2402:

Every patent must contain a written description of the invention sufficient to enable a person skilled in the art to which the invention pertains to make and use the invention. **Where the invention involves a biological material and words alone cannot sufficiently describe how to make and use the invention in a reproducible manner**, access to the biological material may be necessary for the satisfaction of the statutory requirements for patentability under 35 U.S.C. 112.

In the present situation, it appears that the Examiner believes that words alone cannot sufficiently describe the biological materials on page 34 of the specification. Thus, as provided

for by the Biological Deposit Rules an acceptable biological deposit of these materials has been provided under the terms of the Budapest Treaty.

Moreover, phage library constructs were known in the art as described for example in the following publications (both attached):

Vichier-Guerre, et al., Biocatalysis and Biotransformation 21(2); 75-78 (2003),  
“Iterative Cycles of In Vitro Protein Selection for DNA Polymerase”.

Strobel, et al., Sequence Molecular Biotechnology 24(1), May, 2003, “Efficient Display of Two Enzymes of Filamentous Phages Using an Improved Signal”.

Rejections—35 U.S.C. §112, first and second paragraphs

Claims 65 and 66 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite with regard the phages deposited under accession number I-3168, I-3169, I-3170, I-3172, I-3173, I-3174, I-3175, and I-3158 in CNCM on February 27, 2004 and under 35 U.S.C. 112, first paragraph as lacking adequate description.. These phages are expressly described on pages 34-35 of the specification by reference to their accession numbers. An acceptable deposit of these biological materials has been made under the terms of the Budapest Treaty. Such a biological deposit is sufficient to meet the requirements of 35 U.S.C. 112, including the description requirement and that of 35 U.S.C. 112, second paragraph, see MPEP 2403:

Although the issue of the need to make a deposit of biological material typically arises under the enablement requirement of the first paragraph of 35 U.S.C. 112, the issue could also arise under the description requirement ( 35 U.S.C. 112, first paragraph), best mode requirement ( 35 U.S.C. 112, first paragraph) or the requirements of the second paragraph of 35 U.S.C. 112 with respect to the claims.

Consequently, this rejection cannot be sustained because even if the nature of the phages could not be adequately described in words, the requirements of 35 U.S.C. 112 are met by the biological deposits which are expressly described in the original disclosure.

Rejection—35 U.S.C. §112, first paragraph

Claims 1, 3-6, 10, 12, 14-18, 65 and 66 were rejected under 35 U.S.C. 112, first paragraph, as lacking adequate written description for polypeptides “having a mere 95% identity to residues 13-55 of SEQ ID NO: 26”. The claims as amended require that the polynucleotide encode a “polypeptide [that] has DNA polymerase activity”. Therefore the issues in the paragraph spanning pages 7-8 of the Advisory Action have been addressed.

No undue experimentation would have been required by one of skill in the art to identify a polynucleotide that encodes a polypeptide that has DNA polymerase activity since the claim requires a high degree of structural identity, namely “at least 95% identity” to residues 13-555 of SEQ ID NO: 26 as well as mutation of residue W550. Moreover, the disclosure describes how to identify thermostable DNA polymerases, for example, using phage display libraries. Therefore, in view of the significant amount of structural description in the claims defining a narrow subgenus of polypeptides encoded by the claimed polynucleotides, the high level of skill in the molecular biological arts, as well as the explicit direction in the specification for the identification of thermostable enzymes, including exemplification of numerous kinds of polypeptides having enzymatic activity, no undue experimentation would have been required to make and use the invention. Consequently, this rejection cannot be sustained.

Obviousness-Type Double Patenting

Claim 66 was rejected under the judicially-created doctrine of obviousness-type double patenting as being patentably indistinct from claim 15 of U.S. Patent No. 7,417,133. This rejection is moot in view of the amendment of claim 66 to omit the two overlapping species between the two claims. Page 19 of the prior not entered Amendment erroneously


refers to a terminal disclaimer. This terminal disclaimer has not been filed and in view of the in view of the amendment of claim 66 the Applicants submit that such a terminal disclaimer is unnecessary.

Conclusion

This application presents allowable subject matter and the Examiner is respectfully requested to pass it to issue. The Examiner is kindly invited to contact the undersigned should a further discussion of the issues or claims be helpful.

Respectfully submitted,

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MAIER & NEUSTADT, L.L.P.  
Richard L. Treanor

A handwritten signature in cursive script, appearing to read "Thomas Cunningham", written over a horizontal line.

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